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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,928	04/26/2001	Philippa Marrack	2879-76	2069

22442 7590 10/18/2004

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EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/844,928	MARRACK ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *4-8,10-13 and 18-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,9 and 14-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's amendment and remarks, filed 8/02/04, are acknowledged.

2. Claims 34-51 have been canceled.

Claims 4-8, 10-13, and 18-33 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Claims 1-3, 9, and 14-17 are being acted upon.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 16-17 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record as set forth in the action mailed 4/27/04.

Specifically, the specification provides insufficient evidence that the claimed formulations would comprise effective vaccine formulations.

Applicant's arguments, filed 8/02/04, have been fully considered but they are not persuasive. Applicant argues, "The present inventors have provided a novel adjuvant for the stimulation of memory T cells, the effect of which has been demonstrated. Therefore, to combine the adjuvant with a vaccinating antigen for use as a vaccine is enabled, as there are many vaccinating antigens already known in the art that could be used with the adjuvant of the claimed invention to provide a vaccine that elicits an immune response against the vaccinating antigen."

Applicant is advised that the claims drawn to a vaccine adjuvant have not been rejected for lack of enablement. The rejected claims are drawn to vaccines. To be enabled, a vaccine adjuvant need only provide minimal stimulation of a generic

immune response. The enablement bar for a vaccine is higher. Given the inherent unpredictability of physiologic processes, it is incumbent upon Applicant that the specification provide an enabling disclosure commensurate in scope with the breadth of the claims. In the instant case, the rejected claims are broadly drawn to vaccines for the prevention or treatment of both cancers and infectious diseases. The minimal disclosure of a single example in which no vaccines are disclosed, no diseases are prevented nor treated, and no *in vitro* models suitable for studying any diseases are even disclosed, cannot be considered to be enabling. Thus, Applicant's mere argument that "vaccination has been known for years" cannot enable the vaccines of the instant claims.

Applicant argues that the Bodey et al. reference teaches that a tumor vaccine can provide a patient with some benefit.

It is the Examiner's position that a slight delay in initial disease progression at the cost of a much more aggressive disease later comprises a dubious benefit.

Applicant argues that the Cohen reference does not support the Examiner's finding of a lack of enablement. Applicant states, "Applicants are not aware that the role of CTL responses in controlling viruses is or was in doubt and it is believed that the importance of CTL responses in controlling viral infection continues to be demonstrated". Applicant submits an abstract, Spearman 2003, in support.

It remains the Examiner's position that the reference demonstrates the unpredictability of the state of the art. The reference clearly teaches that the best available HIV vaccines have not proven worthy of further testing, thus, there clearly exists a lack of understanding and certainly a great deal of unpredictability in HIV vaccine production. Applicant has provided only a concept in support of broad claims drawn to a vaccine. Said concept provides insufficient support for the claimed invention. Regarding Applicant's question regarding the importance of a CTL response in controlling viral infection, Applicant need look no farther than the Cohen reference for an answer. Cohen refers to a "huge mystery" and states, "No one knows which immune responses [antibody or CTL] correlate with protection". Regarding the Spearman abstract, the single sentence regarding the importance of CTL responses is insufficient support for the invention of the instant claims.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-3, 9, and 14-15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (1998, IDS) in view of Lenardo (1991, IDS), for the reasons of record as set forth in the action mailed 4/27/04.

Applicant's arguments, filed 8/02/04, have been fully considered but they are not persuasive. Applicant argues, that the combined references fail to combine any motivation to arrive at the claimed invention and in fact teach away from the claimed invention. Applicant argues that the Zhang et al. reference does not teach that IL-2 should be inhibited and Lenardo teaches only that IL-2 causes the apoptosis of activated mature T cell and not memory T cells. Applicant concludes by arguing a lack of expectation of success in combining the references.

Applicant has failed to consider that the combined references are viewed in light of that which would be known by the artisan of ordinary skill in the art. The references are not viewed in a vacuum. Accordingly, if the Zhang et al. reference teaches a method for stimulating memory T cells, and the Lenardo reference teaches a method for protecting mature activated T cells (a stage through which memory T cells most likely pass), it would be obvious to the ordinarily skilled artisan to provide an adjuvant (which can be generically defined as a composition for stimulating any aspect of the immune response) comprising an agent that increases IL-15 activity and decreases IL-2 activity. Regarding the argument of a lack of expectation of success, it seems curious that Applicant would put forth this argument considering the fact that the specification provides essentially no data and discloses merely the concept of the claimed adjuvant. It remains the Examiner's position then that the combined references comprise as much expectation of success as does the instant specification and thus render the claimed invention obvious.

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

10. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

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